

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 01 JUN 2005

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Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/EP2004/001785	International filing date (<i>day/month/year</i>) 24.02.2004	Priority date (<i>day/month/year</i>) 21.03.2003
International Patent Classification (IPC) or national classification and IPC A61K35/78		
Applicant UNILEVER PLC		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> <i>sent to the applicant and to the International Bureau</i> a total of sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p style="margin-left: 20px;"><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p style="margin-left: 20px;"><input type="checkbox"/> Box No. II Priority</p> <p style="margin-left: 20px;"><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p style="margin-left: 20px;"><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p style="margin-left: 20px;"><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p style="margin-left: 20px;"><input type="checkbox"/> Box No. VI Certain documents cited</p> <p style="margin-left: 20px;"><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p style="margin-left: 20px;"><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 21.07.2004	Date of completion of this report 30.05.2005	
Name and mailing address of the international preliminary examining authority:		Authorized Officer
<div style="display: inline-block; vertical-align: middle;"> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div>		Thalmair-De Meyere, Telephone No. +49 89 2399-2177



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/001785

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-20 as originally filed

Claims, Numbers

1-17 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 12-14 (industrial applicability)

because:

- ☒ the said international application, or the said claims Nos. 12-14 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
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International application No.
PCT/EP2004/001785

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-17
	No: Claims	
Inventive step (IS)	Yes: Claims	1-17
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-11,15-17
	No: Claims	12-14, see Separate Sheet

2. Citations and explanations (Rule 70.7):

see separate sheet

Section III

Claims 12-14 relate to a subject-matter considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art. 34 (4) a) (i) PCT).

Section V

The presently claimed subject-matter appears to be novel and inventive for the following reasons. None of the documents D 1 to D 4 discloses or suggests to disclose the claimed subject-matter. Hops contain estrogenic activity, however, Applicant has provided evidence (Milligan et al., 1999 and Milligan et al., 2000) that hops does not contain genistein or daidzein. This is because hop plants lack the necessary enzymes to carry out the biochemical synthesis of the specific isoflavones specified in the claims, as is made clear in the specification at page 8, lines 21 to 23. Consequently, hops do not contain any of the specific isoflavones referred to in the claims and therefore hops cannot contain a combination of isoalpha acids and one or more of these specific isoflavones. Accordingly to arrive at a composition as claimed in the present application it is necessary to combine hops, or an isoalpha acid-containing extract thereof, with the specific listed isoflavones obtained from a separate source, such as soy. There is no teaching in the prior art for a person skilled in the art to combine hops, or isoalpha acid-containing extracts thereof, with any of these isoflavones. Furthermore, Applicant has demonstrated unexpected synergistic effects when isoalpha acids are combined with these isoflavones. It is clear from table 3 on page 19 of the application as filed that soy phytoestrogens, despite having no effect on prostaglandin E₂ production on their own, were able to synergistically enhance the inhibition of PGE₂ production by isoalpha acids. This unexpected finding would not have been obvious to a skilled person based on documents D 1 to D 4.

INTERNATIONAL SEARCH REPORT

PCT/EP2004/001785

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K35/78

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE, PASCAL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02/087517 A (BIERGIESSER HELGA ; BEIERSDORF AG (DE); STAEB FRANZ (DE); DOERING THOM) 7 November 2002 (2002-11-07) the whole document	1-17
Y	KEIL D ET AL: "Phytoestrogenes as anti-aging agents" AKTUELLE DERMATOLOGIE 2002 GERMANY, vol. 28, no. 3, 2002, pages 69-73, XP009031640 ISSN: 0340-2541 the whole document	1-17

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

9 June 2004

Date of mailing of the international search report

23/06/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Thalmair, M

INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DATABASE WPI Section Ch, Week 199504 Derwent Publications Ltd., London, GB; Class B02, AN 1995-027623 XP002283452 & JP 06 312924 A (ASAHI BREWERIES LTD) 8 November 1994 (1994-11-08) abstract	1-17
Y	----- HESSE R ET AL: "Demonstration of phytoestrogens in feed plants and hops by means of receptor test!" ZENTRALBLATT FUR VETERINARMEDIZIN. REIHE A. 1981, vol. 28, no. 6, 1981, pages 422-454, XP009031839 ISSN: 0514-7158 page 449 -----	1-17

INTERNATIONAL SEARCH REPORT

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Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 02087517	A	07-11-2002	DE	10121375 A1	07-11-2002
			WO	02087517 A2	07-11-2002
			EP	1392239 A2	03-03-2004
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JP 6312924	A	08-11-1994	NONE		
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